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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,975

06/09/2005

Yves Jongen

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FITCH EVEN TABIN & FLANNERY  
120 SOUTH LASALLE STREET  
SUITE 1600  
CHICAGO, IL 60603-3406

EXAMINER

PALABRICA, RICARDO J

ART UNIT

PAPER NUMBER

3663

MAIL DATE

DELIVERY MODE

11/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,975	<b>Applicant(s)</b> JONGEN ET AL.	
	<b>Examiner</b> Rick Palabrica	<b>Art Unit</b> 3663	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9,11-14,21-25,27,28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,13,27,28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,11,12,14,21-25 and 31-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 10/2/09, which directly amended claims 1 and 23, canceled claim 10, and traversed the rejection of claims in the 4/2/09 Office action, has been entered. The amendment introduced additional structural limitations to the apparatus claims.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Response to Arguments***

2. Applicant traversed the examiner's assertion that "process limitations, as well as statements of intended or desired use, do not patently distinguish the claimed structure over that of a reference, as long as the structure of the cited reference is capable of performing the intended use." This traverse specifically refers to the functional language, "permits inflow and outflow of target material" and "provide an essentially turbulent vortex flow of the target fluid inside the cavity."

Art Unit: 3663

In support of his argument, applicant cites: a) MPEP 2173.05, “[t]here is nothing inherently wrong with defining some part of an invention in functional terms”; b) *In re Venezia*, 530 F.2d 956, 189 U.S.P.Q. 149 (CCPA 1976); MPEP 2173.05(g) (“the Court held that limitations such as ‘members adapted to be positioned’ and ‘portions ... being resiliently dilatable whereby said housing may be slidably positioned’ serve to precisely define present structural attributes of interrelated component part of the claimed assembly.”) Underlining provided by examiner.

The examiner disagrees.

As to argument a), there is no inconsistency between the examiner’s position and this section of the MPEP cited by applicant. The examiner considered the functional language of applicant’s claims and demonstrated that the applied art is capable of meeting the functional limitations.

As to argument b), *In re Venezia* pertains to a completely different type of invention and set of claims, and applicant’s traverse based on this case law is misplaced.

First, *In re Venezia* pertains to a splice connector having interrelated parts to be assembled in the field, to form a completed connector. Thus, the claims are directed to a group or a “kit” of interrelated parts. Applicant’s invention is NOT a “kit” that requires field assembly.

Second, as applicant himself admits, the limitations he cites in *In re Venezia* pertain to structural attributes the individual parts must possess prior to

Art Unit: 3663

their assembly so that the completed product (i.e., a connector) can be properly fitted to one another.

The inlet and outlet of applicant's apparatus are pre-manufactured into the metallic insert and they do not need to be assembled and fitted from individual parts to form a whole. Thus, the findings in the cited case law are irrelevant to applicant's claimed invention, and applicant's argument has no basis.

3. Upon further review of the claims, the examiner noted that claim 30 is directed to the non-elected species C in Figs. 2-4. Accordingly, claim 30 is withdrawn from consideration in this Office action.

If applicant is of a different opinion, this claim is still unpatentable because it does not have a proper antecedent basis for "the second wall portion" and therefore does not comply with the requirements of 35 U.S.C. 112, second paragraph. See also section 7 below.

Accordingly, claims 1-6, 11, 12, 14, 21-25, and 31-37 are examined in this Office action. Claims 8, 9, 13, 27, and 28 were previously withdrawn from consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6, 11, 12, 14, 21, 22, and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

Art Unit: 3663

out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites in the preamble the subcombination of a “device” that is inconsistent with the body of the claim that recites limitations directed to the combination of the device and the accelerated charged particle beam. The preamble does not positively recite the beam as a structural element of the claimed invention because said beam is recited in the statement of intended use of the device. However, the body recites the beam as part of the device (e.g., see line 16).

This inconsistency between the preamble and body of the claim presents the question as to whether the claim recites a combination or subcombination. There is insufficient antecedent basis for the limitation that is directed to the combination rather than to the subcombination because not all devices for radioisotope production use a beam of accelerated charge particles.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6, 21-25, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Kilbourn et al., “A Simple <sup>16</sup>O Target for <sup>18</sup>F

Art Unit: 3663

Production”, Int. J. Appl. Radiat. Inst. Vol. 35 (1984) or Link et al., “Irradiation of Water to Improve the Specific Activity of Oxygen-15 Produced from Oxygen-16”, IVth International Workshop on Targetry and Target Chemistry (1991) or Lindner et al., “Accelerator Production of  $^{18}\text{F}$ ,  $^{123}\text{Xe}$  ( $^{123}\text{I}$ ),  $^{211}\text{At}$ , and  $^{38}\text{S}$ ”, IAEA-SM-171/63 (1973).

Kilbourn et al.

Kilbourn et al. disclose a device for producing  $^{18}\text{F}$  from oxygen-18 water.

As to claims 1, 21 and 23, applicant’s claim language reads on Kilbourn et al. (see Fig. 1) as follows: a) “irradiation cell with a metallic insert and a cavity” reads the target body having a water cavity and a stainless steel flange (see also page 599, paragraph bridging cols. 1 and 2); b) “pump” reads on the expedient for flowing the oxygen-18 water target into the system.

Kilbourn et al. teach that “cooling of the target is absolutely necessary” (see page 600, col. 2, lines 1+). Applicant’s claim language, “external heat exchanger”, reads on the expedient for the system of cooling the target. The claims do not define the structure of said heat exchanger, and absent such definition, the examiner interprets the claim broadly and reads the heat exchanger on any and all forms of said expedient, including that in Kilbourn et al.

Kilbourn et al. further teach that an operator monitors the “pressure increase during irradiation”. Applicant’s claim language, “pressurizing device”, reads on the expedient for providing the increased pressure during irradiation. The claims do not define the structure of said pressurizing device, and absent

Art Unit: 3663

such definition, the examiner interprets the claim broadly and reads it on any and all means for pressurizing the system, including the above added heat sources.

Note from Fig. 1 that the irradiation window is substantially planar and positioned perpendicularly to the accelerated charged particle beam.

As to the limitation, “inlet configured to direct the target fluid flow (1) perpendicular to the irradiation window and (2) to an impact point of the accelerated charged particle beam in the irradiation window so that the inflow hits the window head-on with the beam, note that the recitation that an element is “configured to” perform or “configured for” performing a function does not constitute a limitation in any patentable sense, i.e., it only requires the capability to perform (e.g., see *In re Hutchison*, 69 USPQ 138 69, or *National Presto Indus. V. West Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996). The apparatus in the cited reference enables or permits the function recited in the claims to take place, and therefore meets the claim limitations.

Note further the claims do not define the geometrical shape of the beam, and absent such definition, the examiner interprets the claim broadly and reads “beam” on any and all beam geometries including a planar geometry.

As to item (1) in the above cited limitation, target inlet L2 of Kilbourn et al. directs the target fluid flow perpendicular to the substantially planar Havar window

As to item (2), target inlet L2 of Kilbourn et al. directs the target fluid flow to an impact point of a beam (e.g., a planar one) so that this in flow meets the beam head on. As presently set forth, there can be one or more impact points

Art Unit: 3663

between the target inflow and the beam. The Federal Circuit could not have been clearer on this matter when it cautioned:

*"This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase, 'comprising,'" KCJ Corp v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000).*

Clearly, Kilbourn et al. meet the claim limitations.

As to Fig. 1 of Kilbourn et al. showing the claimed orientation of the target inlet and the beam, note that while patent drawings are not drawn to scale, relationships clearly shown in the drawings of a reference patent cannot be disregarded in determining the patentability of the claims. See In re Mraz, 59 CCPA 866, 455 F.2d 1069, 173 USPQ 25 (1972).

Link et al.

Link et al. disclose a device for producing radioisotopes.

As to claims 1, 21 and 23, applicant's claim language reads on Link et al. (see Fig. 1) as follows: a) "irradiation cell with a metallic insert and a cavity" reads on the aluminum flow through chamber having a water cavity and an aluminum window (see also page 599, paragraph bridging cols. 1 and 2); b) "pump" reads on the Teflon pumps.

Link et al. teach "cooling of the window" (see page 149, col. 1, 1<sup>st</sup> full paragraph). Applicant's claim language, "external heat exchanger", reads on the expedient for the system of cooling the window.

Art Unit: 3663

Applicant's claim language, "pressurizing device", reads on the inherent heat produced by the pump action and the heat added to the target by the irradiating particles.

Note from Fig. 2 that the irradiation window is substantially planar and positioned perpendicularly to the accelerated charged particle beam. See discussion on Killbourn et al. regarding the other claim limitations.

Lindner et al.

Lindner et al. disclose a device for producing radioisotopes.

As to claims 1, 21 and 23, applicant's claim language reads on Lindner et al. (see Figs. 1-4) as follows: a) "irradiation cell with a metallic insert and a cavity" reads on the stainless steel target holder with a cavity; b) "pump" reads on pump (D); c) "external heat exchanger" reads on cooler (B).

Applicant's claim language, "pressurizing device", reads on the inherent heat produced by the pump action and the heat added to the target by the irradiating particles.

Note from Fig. 2 that the irradiation window is substantially planar and positioned perpendicularly to the accelerated charged particle beam. See discussion on Killbourn et al. regarding the other claim limitations.

Claims 2-4, 22 and 33-37 are process limitations and not structural limitations of the claimed apparatus. Additionally, claims 1 and 23 recite statements of intended or desired use, including, "for producing a radioisotope

Art Unit: 3663

from a target fluid ...”, “for generating flow of target fluid...”, “provide an essentially turbulent vortex in the flow of target fluid inside the cavity”, etc. These process limitations clauses, as well as statements of intended use do not serve to patentably distinguish the claimed structure over that of the reference, as long as the structure of the cited references is capable of performing the intended use.

See MPEP 2111-2115.

See also MPEP 2114 that states:

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531.

[A]pparatus claims cover what a device is, not what a device does.” Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525, 1528.

As set forth in MPEP 2115, a recitation in a claim to the material or article worked upon does not serve to limit an apparatus claim.

Any one of the systems in the cited references is capable of being used in the same manner and for the intended or desired use as the claimed invention. Note that it is sufficient to show that said capability exists, which is the case for the cited references.

See also the discussion of “configured to” in Killbourn et al.

As to the limitation, “to create a vortex in the flow of the target fluid inside the cavity”, applicant has not defined the magnitude of the so-called vortex.

Absent such definition, the examiner interprets the term broadly and reads it on

Art Unit: 3663

any vortex level created inside the cavity. Any one of the apparatus in the cited references inherently creates some level of vortex inside the cavity because of the fluid flow into said cavity. Such vortex creation cannot be prevented because of the fluid disturbance cause by the flow.

As to claims 5, 6 and 32-34, these limitations are matters of design and/or optimization. The size of the cavity is a design constraint that can be imposed by the user of the device, which size can be specified so that the apparatus matches the requirements of its application. Additionally, the cavity size for any specific application has to be optimized in order to achieve a proper balancing of competing factors. For example, a larger cavity size may be more expensive but can generate more radioisotopes than a smaller cavity. As to matters of optimization within prior art conditions or through routine experimentation, see MPEP 2144.05 II.A.

6. Claims 12, 14 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilbourn et al., who teach internal cooling (see Fig. 2).

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Kilbourn et al. or Link et al., or Lindner et al. The location of the inlet being along the central axis is a matter of design and/or optimization.

As discussed in section 5 above, any one of the cited references teach the claimed limitation, "inlet configured to direct the target fluid flow (1) perpendicular

Art Unit: 3663

to the irradiation window and (2) to an impact point of the accelerated charged particle beam in the irradiation window so that the inflow hits the window head-on with the beam.

The “beam” can be a planar beam and any location of the inlet in any of the three references that meets (1) inherently meets (2) in the above limitation. Thus, the choice of the location of the inlet in said references may be dictated by either a) the requirements imposed by the user of the apparatus, or b) any physical constraints, e.g., obstructions that may be present in the backside of the apparatus that must be avoided.

Note: The examiner indicated in section 3 above that claim 30 is withdrawn from consideration being directed to the non-elected species. If applicant is still of a different opinion, then this claim is rejectable for the same reason as that given for claim 11.

### ***Conclusion***

8. This is a continuation of applicant's earlier application with the same serial number. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3663

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 571-272-6880. The examiner can normally be reached on 6:00-4:30, Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jack Keith can be reached on 571-272-6878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3663

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rick Palabrica/  
Primary Examiner, Art Unit 3663

November 9, 2009